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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/721,318 | 11/25/2003 | Robert L. Dow | 17082AZ (PCI0118C) | 7093 |

7590 01/10/2006

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EXAMINER

DAVIS, ZINNA NORTHINGTON

ART UNIT PAPER NUMBER

1625

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,318

Applicant(s)

DOW ET AL.

Examiner

Zinna Northington Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 50-54, 57, 58 and 100-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) 3-49, 55, 56, and 59-99 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-104 are pending.
2. Claims 50-54, 57, 58 and 100-104 have been withdrawn from consideration. These claims have not been cancelled.
3. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
4. This action is in response to the Amendment filed October 26, 2005.
5. Based upon the Terminal Disclaimer filed October 26, 2005, the rejections of double patenting over U.S. Patent 6,380,223 and U.S. Patent 6,669,893 are withdrawn.
6. The rejection under 35 U.S.C. §102 (b) over DiMaio et al. is withdrawn based upon the deletion of the radical Z-het.

Response to Applicants' Remarks

About the Restriction/Election

Applicants confirm that the compound of Example 76 was elected and note that the restriction requirement has been made final.

Applicants also note that the Office Action indicates that claims 1-49, 55, 56, and 59-99 are generic to the claimed invention and that these claims were examined with respect to the elected species.

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It is the Examiner's position:

- The restriction requirement has been made final.
- The instant claims have not been amended to the scope of the examined subject matter.
- As such, the Examiner will again extend the examination beyond the elected species.

Response to Applicants' Remarks

About the Improper Markush Group

Applicants note that the Office Action indicates that the improper Markush rejection would be withdrawn if the claims are amended so that A is A-1; D, E, and F are C; X is CH₂; R₁ is Z-aryl; and that Z is absent.

Applicants also note that prior art was not found when searching the elected species. The Office Action indicates that the search was expanded. The only document cited in the Office Action is DiMaio et al, which is no longer relevant. As a result, Applicants are not making the suggested amendments to claim 1.

It is the Examiner's position:

- The improper Markush objection is maintained.
- It is true the elected species is deemed allowable. However, all chemical compounds within the definition of formula I are not.
- As such, the search is extended beyond the elected species.

7. Claims 1-49, 55, 56, and 59-99 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the

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Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

8. Claims 1-49, 55, 56, and 59-99 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnish, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are A, B, C, D, E, F, X, and R₁.

9. The examined subject matter is as follows:

A compound of formula I wherein A is A-1; D, E, and F are C; X is CH₂; R₁ is Z-aryl; and Z is absent. The radicals not defined above are as recited in claim 1.

Amending the claims to the examined subject matter would overcome the improper Markush rejection.

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10. If the examined subject matter is examined beyond the elected species, the following rejection would be applicable.

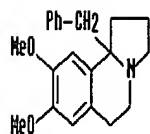
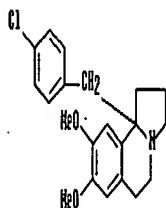
11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

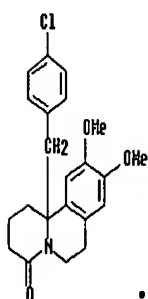
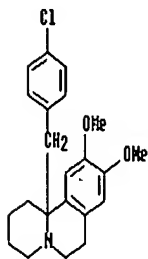
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Houlihan et al (Reference A).

The instantly claimed compounds are disclosed. At column 3, lines 20-25, see compound VIII. At column 7, see compounds (c) and (d). At column 9, lines 15-20, see compound (a). The claims are fully met when A is A-1; D and F are C; E is N; X is CH₂; and R₁ is Z-aryl. The compounds are depicted below:



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13. Claims 3-49, 55, 56, and 59-99 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim (as it read upon the examined subject matter) and any intervening claims.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

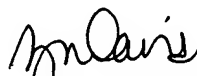
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

16. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Zinna Northington Davis
Primary Examiner
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